an outside surface of the stent, and the stent includes a heparin-based coating over the covering on the inside surface of the stent.

REMARKS

In the Office Action, the drawings, the specification, and claims 3, 8, 16, 19, 30, and 35 were objected to; claims 1-3, 9-15, 29, 30, and 36 were rejected under 35 U.S.C. §102(e) as being anticipated by Phelps et al. (U.S. Patent No. 6,290,728); claims 1, 9-15, 29, and 36 were rejected under 35 U.S.C. §102(b) as being anticipated by Knudson et al. (U.S. Patent No. 5,755,682); claims 4-8, 16-28, and 31-35 were rejected under 35 U.S.C. §103(a) as being unpatentable over Phelps et al. in view of Lee (U.S. Patent No. 5,123,917); claims 3-8, 16-28, and 30-35 were rejected under 35 U.S.C. §103(a) as being unpatentable over Knudson et al. in view of Lee; and claims 29-36 were rejected under an obvious-type double patenting rejection as being unpatentable over claims 1 and 2 of Phelps et al. in view of Lee.

To obviate the objection to the drawings, Applicants submit herewith a Request for Drawing Change Approval along with a proposed drawing change to Fig. 1. By this Request, Applicants propose deleting the reference label "AO" from Fig. 1. Upon the Examiner's approval of the proposed change to Fig. 1, Applicants will defer the submission of formal drawings incorporating the proposed change until receipt of a Notice of Allowance. Applicants respectfully request the withdrawal of the drawing objection.

To obviate the objection to the specification and claims 3, 8, 16, 19, 30, and 35, Applicants have amended the specification and claims 3, 8, 16, 19, 30, and 35. In particular, Applicants have amended the specification at page 8, paragraph 27 to spell

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out the acronym "PTFE" and to clarify what that acronym stands for when used throughout the rest of the specification. Applicants also have amended each of claims 3, 8, 16, 19, 30, and 35 to spell out the acronym "PTFE." The amendments to those claims in no way narrows their scope, as PTFE and polytetrafluoroethylene are one and the same. Applicants respectfully request the withdrawal of the objections to the specification and claims.

Claims 1, 16, 17, and 29 are the only independent claims currently pending in this application. Claims 1 and 29 were rejected under 35 U.S.C. §102(e) as being anticipated by Phelps et al. and claims 16 and 17 were rejected under 35 U.S.C. §103(a) as unpatentable over Phelps et al. in view of Lee. Claim 29 was additionally rejected in a obvious-type double patenting rejection over claims 1 and 2 of Phelps et al. in view of Lee. For the reasons explained below, the above rejections should be withdrawn.

Claims 1 and 29, as amended, each recite, among other things, a stent having a "covering on an inner surface portion and an outer surface portion of the stent." Claim 16 recites, among other things, that "the stent includes a covering having expandable polytetrafluoroethylene that covers substantially all of an inside surface and an outside surface of the stent."

The Phelps et al. reference is directed to a left ventricular conduit adapted to be positioned in the myocardium to provide blood flow between the heart chamber and the coronary artery. The Phelps et al. reference also discloses that the various stent embodiments disclosed can be lined with various materials, including PTFE, to provide for ease of blood flow through the stent. In the Office Action at page 5, the Examiner

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acknowledges that "Phelps . . . does not disclose explicitly that the outside surface is also covered with PTFE." (Office Action, p. 5, para. 13.) Thus, the Phelps et al. reference fails to disclose each and every element recited in claims 1 and 29, as amended, and therefore does not anticipate those claims. For at least this reason, the Section 102 rejection of claims 1 and 29, and their respective dependent claims 2, 3, 9-15, 30, and 36, should be withdrawn.

In rejecting independent claims 16 and 17, the Examiner relies on the Lee reference, in combination with the Phelps et al. reference. (Office Action, p. 5.) However, the Phelps et al. reference is being relied on as prior art under 35 U.S.C. §102(e). Since this application was filed after November 29, 1999, under the provisions of 35 U.S.C. § 103(c), an obviousness rejection under 35 U.S.C. § 103(a) can be overcome by showing that the subject matter of the Phelps et al. reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. Applicants supply a statement on a separate sheet of this response, made by Applicants' representatives, regarding the ownership of this application and the Phelps et al. reference. Applicants respectfully submit that in light of this statement, the Section 103(a) rejection should be withdrawn.

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Applicants' R pres ntative of Record Statement of Common Ownership Under M.P.E.P. §706.02(l)(2)

Under the provisions of M.P.E.P. §706.02(I)(2), Applicants' undersigned representative of record supplies the following statement to the effect that this application and the Phelps et al. patent were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same organization:

This application, U.S. Patent Application No. 09/917,655, filed July 31, 2001, in the name of Peter Boekstegers et al., and U.S. Patent No. 6,290,728, filed as U.S. Application No. 09/369,048 on August 4, 1999, in the name of David Y. Phelps et al., were, at the time the invention of this application was made, both owned by Percardia, Inc.

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In light of the above Statement of Common Ownership, the Section 103(a) obviousness rejection of independent claims 16 and 17, and of dependent claims 4-8, 18-28, and 31-35, based on Phelps et al. in view of Lee should be withdrawn.

Regarding the obviousness-type double patenting rejection of claims 29-36 based on claims 1 and 2 of the Phelps et al. reference in view of Lee, the Examiner asserts in the Office Action at page 7 that "claims 1-2 of U.S. Patent No. 6,290,728 disclose the claimed invention except for a covering that includes expandable PTFE." The Examiner relies on the Lee reference for the alleged teaching of a covering and a heparin coating. (Office Action, pp. 7-8.)

An obviousness-type double patenting rejection is only appropriate if the claimed subject matter of an application claim is not patentably distinct from the subject matter claimed in a commonly owned patent. See M.P.E.P. 804 II(B)(1). According to the M.P.E.P. and case law, the analysis required to support an obviousness-type double patenting rejection parallels the guidelines for a Section 103 obviousness rejection and the following *Graham v. John Deere Co.* inquiries must be employed:

(A) Determine the scope and content of a patent claim and the prior art relative to a claim in the application at issue;
(B) Determine the differences between the scope and content of the patent claim and the prior art as determined in (A) and the claim in the application at issue;
(C) Determine the level of ordinary skill in the pertinent art; and
(D) Evaluate any objective indicia of nonobviousness.

(See M.P.E.P. §804(II)(B)(1).)

M.P.E.P. §804(II)(B)(1) further requires that

> [a]ny obviousness-type double patenting rejection should make clear:
>
> (A) The differences between the invention defined by the conflicting claims - a claim in the patent compared to a claim in the application; and

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(B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent.

In considering the latter, the disclosure of the patent may not be used as prior art. M.P.E.P. §804(II)(B)(1). Thus, the inquiry is limited to the differences in the elements recited in the application patent claims, without resort to the patent disclosure.

The obviousness-type double patenting rejection set forth in the Office Action does not satisfy these requirements of M.P.E.P. §804(II)(B)(1) at least because the rejection fails to identify all the differences between the application claims and the patent claims and does not provide reasons with respect to all of those differences that a person of ordinary skill in the art would conclude that the invention defined in the application claims is an obvious variation of the invention defined in the patent claims. Because the requirements for obviousness-type double patenting rejections as set forth in the M.P.E.P. are not satisfied in the Office Action, that rejection should be withdrawn.

Moreover, the double patenting rejection of application claims 29-36 should be withdrawn because patent claims 1 and 2 of the Phelps et al. reference do not disclose numerous nonobvious recitations in claims 29-36. In particular, the Phelps et al. patent claims do not recite at least "a stent that includes a configuration having sufficient radial strength to resist deformation from contractile forces experienced during a cardiac cycle and sufficient flexibility in a compressed state and a deployed state to permit passage to a myocardial site and remain patent when implanted in the site" or "delivering the stent in a compressed state into a passage at the myocardial site," as recited in claims 29-36.

Rather, claim 1 of the Phelps et al. reference recites a bypass conduit for use in a wall of a heart, comprising "a hollow conduit having an interior and an exterior and

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adapted to be positioned in the heart wall between the coronary artery and a chamber in the heart, wherein the conduit has an attachment mechanism on at least one end adapted to anchor the conduit in place." Claim 2 of Phelps et al. recites all of the features of claim 1 and additionally recites that "the conduit is self-expandable." Claims 1 and 2 of the Phelps et al. reference thus are utterly silent with respect to the configuration providing the sufficient radial strength to resist deformation from contractile forces experienced during a cardiac cycle and the flexibility recited in application claims 29-36, as well as the delivering and expanding steps. Indeed, the Examiner has not set forth these differences between between patent claims 1 and 2 and application claims 29-36. Nor has the Examiner explained why a person of ordinary skill in the art would conclude that application claims 29-36 are an obvious variation of patent claims 1 and 2. See M.P.E.P. §804(II)(B)(1). For at least these reasons, the double patenting rejection of claims 29-36 should be withdrawn.

Independent claims 1 and 29 also were rejected under 35 U.S.C. §102(b) as being anticipated by Knudson et al., and independent claims 16 and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Knudson et al. in view of Lee. Claims 1 and 29, as amended, each recite, among other things, a stent having a "flexibility in a compressed state and a deployed state" and a "covering on an inner surface portion and an outer surface portion of the stent." Independent claim 16 recites, among other things, a stent having "sufficient flexibility in a compressed state and a deployed state . . . wherein the stent includes a covering." Independent claim 17, as amended, recites a method that includes, among other things, a stent having "sufficient

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flexibility in a compressed state and a deployed state" and "applying a covering to the stent."

The Knudson et al. reference pertains to a method and apparatus for performing coronary artery bypass surgery that establishes a channel leading directly from a chamber of a heart into a coronary artery. In each of the embodiments described in the Knudson et al. reference, a bypass stent includes a portion for insertion into the heart wall between the heart chamber and the coronary artery. In the embodiments of Figs. 1A-9, the Knudson et al. reference discloses either an L-shaped or T-shaped stent 10, 10'. The Knudson et al. reference further discloses that the stents 10, 10' may have an anchor arm 20, 20' for insertion into the heart wall that comprises a plurality of rings 17 surrounded by a membrane 18, as shown in Figs. 3A-3C.

The L- and T-shaped stents of Figs. 1A-3C are described as embodiments of the invention for use with either an open or closed chest approach (see, e.g., col. 12, lines 59+ and col. 21, lines 4+). Both of those approaches require surgical access to the coronary artery and heart wall to implant the stent 10, 10'. The open chest approach is described starting at col. 17 and is shown in Figs. 4-9, and the closed chest approach is described beginning at col. 21. In essence, both the open and closed chest approaches are surgical approaches whereby the superficial wall 36 of the coronary artery 30 is longitudinally incised. A channel 50 is then initiated into the deep coronary artery wall 40 and into the musculature 42 (i.e., heart wall) of the heart chamber and to the chamber. Once the channel 50 extends through the entire thickness of the heart wall, the anchor arm 12, 12' of the stent 10, 10', as shown in the embodiments of Figs. 1A-3C, is inserted into the channel 50 and the arms 14, 14', and/or 16 of the stent 10, 10'

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are then seated within the lumen 48 of the coronary artery 30 through the incision made previously. Thus, as shown in Figs. 1A-9, the stent embodiments 10, 10' are implanted in the patient's heart in an expanded configuration.

The Knudson et al. reference further discloses an alternative embodiment of a stent in Figs. 10-17B which may be implanted using a catheter-controlled approach, as opposed to the surgical approaches described above. In that catheter approach, an intracoronary catheter 120 is inserted through the femoral artery 124 and eventually into the coronary artery 30 to a desired location. A balloon 130 located on the distal end of the catheter 120 is inflated causing a hollow, expandable stent 134 to be seated against the coronary arterial walls 36, 40. The catheter balloon 130 is then deflated and the catheter 120 is withdrawn. Next, an intraventricular catheter 140 is inserted into the left ventricle and a channel 50 is ablated through a wall 42 of the left ventricle using an ablating tip 142 on the catheter. The catheter 140 is withdrawn and a second intraventricular catheter 160 is inserted into the left ventricle. An inflatable balloon 60 on the distal end of the catheter 160 carries a stent-forming device 61. The stent forming device 61 comprises a spiral sheet, as shown in Figs. 15A and 15B. The device 61 has an initial, reduced diameter, as shown in Fig. 15A, and expands via the balloon 60 to a cylinder of larger diameter, as shown in Fig. 15B, such that the device 61 is retained within the channel 50.

In the Section 102(b) rejection of claims 1 and 29, the Examiner asserts that Knudson et al. discloses a stent with an intraventricular portion 61 that has "flexibility in a compressed and a deployed state." The Examiner relies on the stent embodiment shown in Figs. 14D, 15A, and 15B to support this assertion. (Office Action, p. 4.) The

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Examiner further asserts that the stent has a covering 18, and refers to col. 14, lines 1-10 (i.e., the embodiment of Figs. 3A-3C) of the Knudson et al. reference to support this assertion. Thus, in the 102(b) rejection of claims 1 and 29, the Examiner relies on the stent embodiment of Figs. 14D, 15A, and 15B for the alleged teaching of a stent having a flexibility in a compressed state and a deployed state, but relies on the stent embodiments of Figs. 1A-3C for the covering. However, the Knudson et al. reference does not disclose that stent embodiments of Figs. 1A-9, have a "flexibility in a compressed and a deployed state" That is, Knudson et al. fails to disclose that the stent embodiments of Figs. 1A-9 have a compressed state. Indeed, those stent embodiments are disclosed as being used with the open and closed chest approaches approaches in which the stents are inserted in an already expanded configuration and the Knudson et al. reference does not teach or otherwise suggest that those stents are capable of being placed in a compressed state. Further, in the stent embodiments of Figs. 10-17B, Knudson et al. specifically omits, thereby failing to disclose or otherwise suggest, a covering on those collapsible/expandable stent configurations. Rather, the only covering, i.e., the covering 18 described with reference to Figs. 3A-3C, that Knudson et al. discloses is used with the noncompressible stent embodiments of Figs. 1A-9. By explicitly disclosing a covering 18 for use with the noncompressible stent embodiments of Figs. 1A-9 and failing to suggest such a covering for the compressible stent embodiments of Figs. 10-17B, the Knudson et al. reference fails to disclose or otherwise suggest, a stent having both a "flexibility in a compressed state and a deployed state" and a covering, and thus fails to anticipate claims 1 and 29.

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Moreover, because the Knudson et al. reference specifically teaches applying a covering to the noncompressible stent embodiments of Figs. 1A-9, but omits any teaching or other suggestion of supplying a similar covering on the compressible/expandable stent embodiments of Figs. 10-17B, the Knudson et al. reference teaches against the combination of a stent having both a covering and a flexibility in a compressed state and a deployed state, and accordingly skilled artisans would not have been motivated to modify the stent disclosed in the embodiments of Figs. 10-17B of Knudson et al. with the inner layer 10 and outer layer 20 disclosed in the Lee reference.

For at least these reasons the Section 102 and 103 rejections of independent claims 1, 16, 17, and 29, and their respective dependent claims 4-15, 18-28, and 30-36, based on either Knudson et al. alone or Knudson et al. in combination with Lee should be withdrawn.

Regarding dependent claims 9, 23, and 36, the Examiner asserts that Knudson et al. discloses a stent having a flared end. The Examiner alleges that the "tongue" disclosed by Knudson et al. at col. 9, lines 12-15 corresponds to Applicants' claimed "flared end." As commonly understood, a "flare" is "an expanding or opening outward." *The American Heritage College Dictionary*, 3d Ed. 1993. This is entirely consistent with Applicants' use of that term throughout the specification, including the claims. In contrast, Knudson et al.'s disclosure of a "tongue" does not teach or suggest a flared end. In particular, the Knudson et al. reference contains only a passing reference to such a "tongue" embodiment in the disclosure at col. 9, lines 12-15, relied on by the Examiner, stating that the "interlocking [between the first apparatus and the second

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apparatus] could be accomplished by a tongue on the second apparatus that slips into a groove on the first apparatus." The Knudson et al. reference provides no illustration of that "tongue" embodiment. A tongue protruding from the second apparatus 61 such that is fits with a groove provided on the first apparatus 36, as taught by Knudson et al. does not equate to the end of the second apparatus being flared. Such a protruding strip has a completely different structure than a flared end. This finds support in the common meaning of "tongue," which is defined by *The American Heritage College Dictionary*, 3d Ed. 1993, as "[a] protruding strip . . . that fits into a groove on the edge of another board." Thus, for at least this additional reason, the rejections of claims 9, 15, and 36 based on either Knudson et al. alone or Knudson et al. in view of Lee should be withdrawn.

Should the Examiner maintain the position that the Knudson et al. reference's disclosure of a "tongue" equates to Applicants' recited "flared end," Applicants respectfully request that, in the next Office communication, the Examiner clearly explain how the recitation "flared end" in Applicants' claims is being interpreted and how Knudson et al.'s disclosure of a "tongue" reads on that interpretation.

Applicants respectfully request the withdrawal of the outstanding objections and rejections and the timely allowance of the pending claims 1-36.

An Appendix is attached showing the changes made to the specification and claims as a result of this Amendment, with deletion shown by bracketing and additions shown by underlining.

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Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: January 8, 2003

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APPENDIX

This Appendix is being provided in accordance with 37 C.F.R. §§ 1.121(b)(1)(iii) and (c)(1)(ii) showing the changes to the specification and the claims. Deletions are shown in bracketing and additions are shown in underlining. This Appendix is not intended to be part of the application.

Changes to paragraph [027] bridging pages 8 and 9:

In preferred embodiments of the invention, the expandable stents from Orbus Medical Technologies and Stent Tech have a covering of expandable PTFE (polytetrafluoroethylene) material. In the preferred embodiment of the invention, the metal stent is sandwiched between the PTFE material, i.e. the PTFE covers the entire stent, including the inside and outside surfaces.

Changes to claims 1, 3, 8, 16, 17, 19, 29, 30, and 35:

1. (Amended) A method of providing blood flow directly from a heart chamber to a coronary vessel, comprising:

providing a stent that includes a configuration having sufficient radial strength to resist deformation from contractile forces experienced during a cardiac cycle and sufficient flexibility in a compressed state and a deployed state to permit passage to a myocardial site and remain patent when implanted in the site, wherein the stent includes a covering on an inner surface portion and an outer surface portion of the stent; and

expanding the stent to deploy the stent in the passage.

3. (Amended) The method of claim [2] 1, wherein the covering includes expandable [PTFE] polytetrafluoroethylene.

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8. (Amended) The method of claim 1, wherein the stent includes a covering having expandable [PTFE] polytetrafluoroethylene that covers substantially all of an inside surface and an outside surface of the stent and the stent includes a heparin-based coating over the covering on the inside surface of the stent.

16. (Amended) A method of providing blood flow directly from a left ventricle to a coronary artery, comprising:

providing a stent that includes a configuration having sufficient radial strength to resist deformation from contractile forces experienced during a cardiac cycle and sufficient flexibility in a compressed state and a deployed state to permit passage to a myocardial site distal to a coronary blockage and remain patent when implanted in the site, wherein the stent includes a covering having expandable [PTFE] polytetrafluoroethylene that covers substantially all of an inside surface and an outside surface of the stent, and the stent includes an antithrombogenic coating over the covering on the inside surface of the stent;

delivering the stent percutaneously in the compressed state into a passage at the myocardial site; and

expanding the stent to deploy the stent in the passage.

17. (Amended) A method of providing blood flow directly from a heart chamber to a coronary vessel, comprising:

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providing a stent that includes a configuration having sufficient radial strength to resist deformation from contractile forces experienced during a cardiac cycle and sufficient flexibility in a compressed state and a deployed state to permit passage to a myocardial site and remain patent when implanted in the site;

applying a covering to the stent;

applying a coating over the covering on an inside surface of the stent; and

delivering the stent into a passage at the myocardial site.

19. (Amended) The method of claim 17, wherein the covering includes expandable [PTFE] polytetrafluoroethylene.

29. (Amended) A conduit for providing blood flow directly from a heart chamber to a coronary vessel, comprising:

a stent that includes a configuration having sufficient radial strength to resist deformation from contractile forces experienced during a cardiac cycle and sufficient flexibility in a compressed state and a deployed state to permit passage to a myocardial site and remain patent when implanted in the site, and

a covering [applied to] on an inner surface portion and outer surface portion of the stent.

30. (Amended) The conduit of claim 29, wherein the covering includes expandable [PTFE] polytetrafluoroethylene.

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35. (Amended) The conduit of claim 29, wherein the conduit includes expandable [PTFE] polytetrafluoroethylene that covers substantially all of an inside surface and an outside surface of the stent, and the stent includes a heparin-based coating over the covering on [an] the inside surface of the stent.

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